K140435

JUN 2 6 2014

510(k) Summary
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28-May-14

American Dental Sleep Medicine, IP, LLC
219 Ridgeview Drive
Wexford, PA 15090

Official Contact:	Mary Beth Rogers, President
Proprietary or Trade Name:	Medley Gold
Common/Usual Name:	Intraoral devices for snoring and obstructive sleep apnea
Classification Name:	LRK - Device, anti-snoring, intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea 21 CFR 872.5570 Class 2
Predicate Devices:	K971794 – Frantz – EMA K113201 – ResMed – Narval CC K023836 – Strong Dental – SUAD

Device Description
The Medley Gold series oral appliance design concept is based upon the use of a standard set of upper and lower trays that have been customized by a dentist that then may have one of three (3) options attached to the trays to act as a Mandibular Repositioning Device (MRD).

The rationale for have a single set of customized trays that may have different MRD methods attached is that some patients have a personal preference and some configurations are more comfortable for them. Therefore rather than having to make another set of custom trays, the dentist may use the same trays and just change the method of MRD, i.e. bands, links, or rods, to the same set of trays.

The principle of advancing a lower tray so that it advances the mandible for the treatment of snoring and / or obstructive sleep apnea is well known and there a number of predicate devices.

The proposed Medley Gold device has three (3) methods of advancing the lower tray based upon the identical designs of 3 already cleared predicate designs.

1) Bands
    a. K971794 – Frantz EMA
2) Links
    a. K113201 – ResMed Narval CC
3) Rods
    a. K023836 – Strong SUAD

Indications for Use
A customized mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Environment of Use
Home, Dental offices, and Sleep laboratories

Predicate Device Comparison:
We selected a predicate for each style of Medley Gold and present them in **Table 1** below.

Table 1 – Rationale for the Predicate Selection

Medley Gold	Frantz EMA (band) K971749	ResMed Narval CC (links) K113201	Strong Dental SUAD (rod) K023836
Common features			
Indications for use	Anti-snoring Mild and moderate OSA	Anti-snoring Mild and moderate OSA	Anti-snoring Mild and moderate OSA
Patient population	18 yo	18 yo	18 yo
Customized trays	Yes	Yes	Yes
Principle of operation	Mandibular advancement	Mandibular advancement	Mandibular advancement
Means of advancement			
Elastomeric bands	Yes		
Link adjustable		Yes	
Rod adjustable			Yes

As can be seen above there are specific predicates for each configuration of the means to advancement, i.e., links, bands or rods. All the predicates and the proposed Medley Gold have the identical indications for use, patient population and environment of use.

We will discuss in more detail each Medley Gold style and the respective predicate in the following tables.

Table 2 – Medley Gold – Band vs. K971794 – Frantz EMA (Band)

	Medley Gold Band	Frantz EMA K971794
Indications for Use	A customized mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.	Treatment nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where advancement of the mandible and opening the bite can increase the patient's air space.

Environments of use	Home, dental and Physician offices, Sleep laboratories	Home, dental and Physician offices, Sleep laboratories
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	No limitation
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the splints by the use of elastic force pulls the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position	Adjustment of the relative position of the splints by the use of elastic force pulls the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position
Design		
Customized tray	Yes	Yes
Molded in supports	Yes	No
Allows lateral and vertical movement	Yes	Yes
Buttons attach to frame to attach bands	Yes	Yes
Framework (support) inserted into upper and lower trays	Yes	Yes
Maximum protrusion of the device	8 mm adjusts in 1 mm increments	8 mm adjusts in 1 mm increments
Adjustment method for setting the amount of protrusion	Elastomeric bands	Elastomeric bands
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water	Yes	Yes
Materials of construction	Durasoft Splint Biocryl Biocryl X glue Supports, nuts, screws Bands	Similar materials

The Medley Gold - Band is viewed as substantially equivalent to the predicate device because:

Indications –
Substantial equivalent to predicate – Frantz EMA – K971794. Indicated for treating snoring and obstructive sleep apnea (OSA).

Technology / Principle of Operation –
Substantial equivalent to predicate – Frantz EMA – K971794. Both devices use a separate tray

design with a means to adjust the lower jaw. The adjustment is a series of elastomeric bands which may be changed by the dentist to alter the mandible advancement. The proposed Medley Gold – Band is using the identical EMA bands.

Materials –
The materials in contact with the patient are standard off-the-shelf dental materials.

Environment of Use –
Similar to predicate – Frantz EMA – K971794. They are used in Home, Dental and Physician offices, and Sleep laboratories.

Patient Population –
Substantial equivalent to predicate – Frantz EMA – K971794. 18 years and older

Discussion – The proposed Medley Gold – band design is substantially equivalent to the predicate Frantz EMA (band) K971749 in all respects and does not raise any new safety or performance concerns.

Table 3 – Medley Gold – Link vs. K113201 – ResMed Narval CC

	Medley Gold Link	**ResMed Narval CC K113201**
Indications for Use	A customized mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Environments of use	Home, dental and Physician offices, Sleep laboratories	Home, dental and Physician offices, Sleep laboratories
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	No limitation
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position
Design		
Customized tray	Yes	Yes

Molded in supports	Yes	No
Allows lateral and vertical movement	Yes	Yes
Mounting screws attach to frame to attach links	Yes	Yes
Framework (support) inserted into upper and lower trays	Yes	Yes
Maximum protrusion of the device	8 mm adjusts in 1 mm increments	15 mm in 1 mm increments
Adjustment method for setting the amount of protrusion	Adjustable links	Adjustable links
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water	Yes	Yes
Materials	Durasoft Splint Biocryl Biocryl X glue Supports, nuts, screws Links	Similar materials

The Medley Gold - Link is viewed as substantially equivalent to the predicate device because:

Indications –
Substantial equivalent to predicate – ResMed Narval CC – K113201. Indicated to reduce or alleviate night time snoring and treat obstructive sleep apnea (OSA).

Technology / Principle of Operation –
Substantial equivalent to predicate – ResMed Narval CC – K113201. Both devices use a separate tray design with a means to adjust the lower jaw. The adjustment is a series of links of different lengths that the dentist may change out.

Materials –
The materials in contact with the patient are standard off-the-shelf dental materials.

Environment of Use –
Substantial equivalent to predicate – ResMed Narval CC – K113201. They are used in Home, dental and Physician offices, and Sleep laboratories.

Patient Population –
Substantial equivalent to predicate – ResMed Narval CC – K113201. 18 years and older

Discussion – The proposed Medley Gold – link design is substantially equivalent to the predicate ResMed Narval CC (link) K113201 in all respects and does not raise any new safety or performance concerns.

Table 4 – Medley Gold – Rod vs. K023836 – Strong Dental SUAD

	Medley Gold Rod	**Strong Dental SUAD K023836**
Indications for Use	A customized mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.	A custom-fitted mandibular repositioning device intended to reduce or alleviate night-time snoring and obstructive sleep apnea.
Environments of use	Home, dental and Physician offices, Sleep laboratories	Home, dental and Physician offices, Sleep laboratories
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	No limitation
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position
Design		
Customized tray	Yes	Yes
Molded in supports	Yes	Yes
Allows lateral and vertical movement	Yes	Yes
Mounting screws attach to frame to attach rods	Yes	Yes
Framework (support) inserted into upper and lower trays	Yes	Yes
Maximum protrusion of the device	8 mm adjusts in 1 mm increments	unlimited
Adjustment method for setting the amount of protrusion	Adjustable rods	Adjustable rods
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water	Yes	Yes
Materials	Durasoft Splint Biocryl Biocryl X glue Supports, nuts, rods, screws	Similar materials

The Medley Gold - Rod is viewed as substantially equivalent to the predicate device because:

Indications –
Substantial equivalent to predicate – Strong Dental – SUAD – K023836. Indicated for treating snoring and obstructive sleep apnea (OSA).

Technology / Principle of Operation –
Substantial equivalent to predicate – Strong Dental – SUAD – K023836. Both devices use a separate tray design with a means to adjust the lower jaw. The adjustment is a series of adjustable rods with the mandible adjustment set by the dentist.

Materials –
The materials in contact with the patient are standard off-the-shelf dental materials.

Environment of Use –
Substantial equivalent to predicate – Strong Dental – SUAD – K023836. They are used in Home, dental and Physician offices, and Sleep laboratories.

Patient Population –
Substantial equivalent to predicate – Strong Dental – SUAD – K023836. 18 years and older

Non-clinical Testing –

FDA has suggested that all intra oral devices will have to demonstrate that the physical properties of the materials used to fabricate the devices are equivalent to that of the predicate device. For the proposed Medley Gold customized oral appliance, all the materials for the customized tray are being used as directed by the manufacturer and are unaltered.

The materials are currently used to make customized trays which are identical to the identified predicates that also use customized trays as their base design. Each design then adds components which are used to advance the lower jaw and hold it in place while the patient sleeps.

These components, bands, links or rods, are similar to the predicates and we performed specific tests to validate these components and the method of attachment to the trays.

However the list of tests, ultimate flexural strength, ultimate flexural modulus, water sorption, water solubility, fracture toughness with modified bending test, relate to the tray materials, all of which are standardized dental materials that are FDA listed.

For those parts of the Medley Gold which are not tray materials, we performed testing to demonstrate that the support components perform as intended

Substantial Equivalence Conclusion –

The sponsor has demonstrated through testing and comparison to the predicates that the proposed device can be found substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

American Dental Sleep Medicine, IP, LLC
C/O Mr. Paul Dryden
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K140435
Trade/Device Name: Medley Gold Series Oral Appliances
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: May 28, 2014
Received: May 29, 2014

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140435

Device Name
Medley Gold series oral appliances

Indications for Use *(Describe)*
A customized mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael E. Adjodha -S
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